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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/763,004

01/22/2004

Paul Poulin

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EXAMINER

FORD, ALLISON M

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 05/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/763,004

Applicant(s)

POULIN, PAUL

Examiner

Allison M. Ford

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,5-31,33-37,39 and 40 is/are pending in the application.
- 4a) Of the above claim(s) 16-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1,5-15,31,33-37,39 and 40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

The amendment to the claims filed on 27 March 2006, does not comply with the requirements of 37 CFR 1.121(c) because the claim listing does not contain a listing of all the claims ever presented for examination in this case, as well as their status. Amendments to the claims filed on or after July 30, 2003 must comply with 37 CFR 1.121(c) which states (emphasis added):

**(c) *Claims.*** Amendments to a claim must be made by rewriting the entire claim with all changes (e.g., additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).

(1) *Claim listing.* All of the claims presented in a claim listing shall be presented in ascending numerical order. Consecutive claims having the same status of “canceled” or “not entered” may be aggregated into one statement (e.g., Claims 1–5 (canceled)). The claim listing shall commence on a separate sheet of the amendment document and the sheet(s) that contain the text of any part of the claims shall not contain any other part of the amendment.

(2) *When claim text with markings is required.* All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of “currently amended,” and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. Only claims having the status of “currently amended,” or “withdrawn” if also being amended, shall include markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as “withdrawn—currently amended.”

(3) *When claim text in clean version is required.* The text of all pending claims not being currently amended shall be presented in the claim listing in clean version, i.e., without any markings in the presentation of text. The presentation of a clean version of any claim having the status of “original,” “withdrawn” or “previously presented” will constitute an assertion that it has not been changed relative to the immediate prior version, except to omit markings that may have been present in the immediate prior version of the claims of the status of “withdrawn” or “previously presented.” Any claim added by amendment must be indicated with the status of “new” and presented in clean version, i.e., without any underlining.

(4) *When claim text shall not be presented; canceling a claim.*

(i) No claim text shall be presented for any claim in the claim listing with the status of “canceled” or “not entered.”

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(ii) Cancellation of a claim shall be effected by an instruction to cancel a particular claim number. Identifying the status of a claim in the claim listing as "canceled" will constitute an instruction to cancel the claim.

(5) *Reinstatement of previously canceled claim.* A claim which was previously canceled may be reinstated only by adding the claim as a "new" claim with a new claim number.

As noted above, the amendment under consideration herein fails to comply with 37 CFR 1.121 because the text of withdrawn claims 16-30 is not present; please note unless a claim is cancelled the entire text as well as the status must be presented. Thus, the amendment could be considered non-responsive. However, in the interest of compact prosecution the amendment at issue will not be considered non-responsive. However, any future responses failing to comply with 37 CFR 1.121 will be held non-responsive, and will not be considered.

#### *Status of Application*

Applicant's amendments filed 27 March 2006 to claims 1, 13, 31 and 37 have been entered. Claims 2-4, 32 and 38 have been cancelled. Claims 1, 5-31, 33-37, 39 and 40 remain pending in the current application, with claims 16-30 being withdrawn from consideration. Claims 1, 5-15, 31, 33-37, 39 and 40 have been considered on the merits.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 and 31-40 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's amended claim 1 is directed to a method for long-term storage of hereditary information, comprising providing a genetic sample comprising lyophilized DNA and sugar, wherein the

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sugars is trehalose or sucrose, in a hermetically sealed UV blocking container under an inert gas, wherein the DNA is substantially free of magnesium; and storing the sample. Applicant's claim 31 further requires a step of placing the sealed UV blocking container into a holding member that is inserted into an aperture of a box that together forms a kit for the long-term storage of hereditary information.

Claims 1 and 31 require the DNA to be substantially free of magnesium; however, the term "substantially free" in claims 1 and 31 is still considered to be a relative term which renders the claim indefinite. In the instant case the specification provides no general guidelines for ascertaining the concentration or amount of magnesium which can be contained within the genetic sample, while still being considered "substantially free" of magnesium; furthermore, there is no art recognized limit relating to the amount of magnesium which can be included in genetic samples, and still be considered "substantially free" of magnesium. The term "substantially free" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Therefore one skilled in the art cannot determine the scope of the claim. The applicants are directed to section 2173.05(b) section D of the MPEP for discussion of the use of the term "substantially."

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5-15, 31, 33-37, 39 and 40 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ando et al (J. Pharm. Sci, 1999), in view of "Kevin Duerinck Genealogy Page" (March 2001) and CATGee, Ltd (Product and Company Info, available before Jan. 2004), and further in view of Cadet et al

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(Biol. Chem, 1997), Kiefer (US Patent 3,907,586), Labconco ("A Guide to Freeze Drying for the Laboratory," ©1997, available Jan. 1988) and Gilbert et al (Current Protocols in Human Genetics, 1998).

Applicant's amended claim 1 is directed to a method for long-term storage of hereditary information, comprising providing a genetic sample comprising lyophilized DNA and sugar, wherein the sugars is trehalose or sucrose, in a hermetically sealed UV blocking container under an inert gas, wherein the DNA is substantially free of magnesium; and storing the sample. Claim 5 requires the inert gas to be nitrogen or argon. Claim 6 requires the UV blocking container to comprise borosilicate. Claims 7-9 require specific amounts of DNA to be included in the sample. Claim 10 requires the DNA to be lyophilized. Claim 11 requires the DNA to be obtained from the blood of a subject. Claim 12 requires the sample to be stored at a temperature between about  $-7^{\circ}\text{C}$  to about  $24^{\circ}\text{C}$ . Claim 13 requires the sample to further comprise EDTA. Claim 14 requires the DNA to be genomic DNA. Claim 15 requires a further step of isolating the DNA.

Applicant's claim 31 is directed to a method for long-term storage of hereditary information, comprising providing a genetic sample comprising lyophilized DNA and sugar, wherein the sugar is trehalose or sucrose, in a hermetically sealed UV blocking container under an inert gas, and placing the sealed UV blocking container into a holding member that is inserted into an aperture of a box that together forms a kit for the long-term storage of hereditary information, wherein the DNA is substantially free of magnesium; and storing the sample. Claim 33 requires the inert gas to be nitrogen or argon. Claim 34 requires sample to comprise greater than 20 ug of DNA. Claim 35 requires the sample to be stored at a temperature between about  $-7^{\circ}\text{C}$  to about  $24^{\circ}\text{C}$ . Claim 36 requires the DNA to be genomic DNA. Claim 37 requires the holder member to hold four hermetically sealed containers of the lyophilized DNA and sugar. Claim 39 requires the box to be made of cardboard. Claim 40 requires the holder member to be made of a transparent plastic.

Ando et al teach a method for providing a genetic sample comprising lyophilized DNA samples that are stable for storage at room temperature (about 25°C, which applicant calls storage at a temperature between about considered to be about -7°C to about 24°C) (See Ando et al, Pg. 127, col. 1). Ando et al do not teach inclusion of magnesium ions or any component that comprise magnesium; therefore the DNA appears to be substantially free of magnesium. Ando et al also teach that by including sugars, such as disaccharides trehalose and sucrose, and the monosaccharide glucose, in the DNA solution, the stability of the lyophilized DNA product is increased (See Ando et al, Pg. 128, col. 1-2 and Table 3 and Figure 2). Ando et al also teach that EDTA in the DNA sample increases stability (See Ando et al, Pg. 127, col. 2- Pg. 128, col. 1). Therefore Ando et al teach a method of providing a genetic sample comprising lyophilized DNA, sugar (including trehalose, sucrose, or glucose), and EDTA (Claims 10, 12, 13, and 15).

Ando et al use 20 ug samples of DNA (See Ando et al, Pg. 127, col. 1); however, it would have been obvious to one of ordinary skill in the art to lyophilize any desired quantity of DNA based on the sample quantity provided or on the needs of the experiments to be carried out. One of ordinary skill in the art would have a reasonable expectation of successfully scaling up the procedure to perform the lyophilization process on any amount of DNA sample provided. It is well established principle in patent law that the mere scaling up of a prior art process capable of being scaled up, does not establish patentability in a claim to an old process or product capable of being scaled up, See *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976). In general, differences in size or proportion do not distinguish the claimed invention from prior art that discloses the same product in a different size or proportion, especially when the difference in size or proportion has no effect on the function of the product (Claims 7-9 and 34).

Though Ando et al teach methods of providing lyophilized DNA and sugar and/or EDTA, wherein the DNA is substantially free of magnesium, they do not teach providing the lyophilized genetic

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sample in a hermetically sealed UV blocking container under an inert gas. However, at the time the invention was made it would have been well within the purview of one of ordinary skill in the art to provide the genetic sample in a hermetically sealed UV blocking container under an inert gas in order to preserve the genetic sample for long-term storage. One of ordinary skill in the art would have been motivated to preserve the genetic sample for long-term storage because personal long-term storage of ones' own DNA has become increasingly popular for security reasons and for family genealogy research. For example, Duerinck suggests archiving ones' family's DNA for future genetic testing, in case a medical problem arises one day, or for genealogical purposes, such as finding relatives. Other companies provide DNA storage services, such as CATGee Ltd, who suggest saving DNA for protection of ones' identity, or as a unique gift (The DNA storage services provided by CATGee Ltd were available before Jan 2004, as evidenced by the article in "UK Trade & Investment" dated 21 April 2003). Therefore, one of ordinary skill in the art would have been motivated to lyophilize their genetic samples, in the method of Ando et al, in order to allow for long-term storage of the genetic sample. Additionally, in order to protect the lyophilized genetic sample from degradation or deterioration during storage, it would have been well within the purview of one of ordinary skill in the art, at the time the invention was made, to store the lyophilized sample in a UV blocking container under an inert gas. One of ordinary skill in the art would have been motivated to store the DNA sample in a UV blocking container because UV rays damage DNA (See Cadet et al, abstract & Fig. 1); therefore it would have been obvious to one of ordinary skill in the art to store the genetic sample in a container that blocks UV rays, such as the UV blocking borosilicate and tin vials of Kiefer (See Kiefer, abstract & col. 3, ln 63-col. 4, ln 9). One would expect the vials of Kiefer to protect the genetic sample from UV damage because Kiefer teaches the vials effectively protect the contained sample from UV damage (See Kiefer col. 3, ln 63-col. 4, ln 9). One of ordinary skill in the art would also have been motivated to store the DNA sample in the above mentioned container under an inert gas, such as nitrogen or argon because oxygen and moisture are detrimental to



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DNA (See Labconco, Pg. 8); therefore it is routine practice to apply vacuum to the sample container and backfill with an inert gas such as nitrogen or argon (See Labconco, Pg. 7, col. 2). One would expect success backfilling the vials of Kiefer with nitrogen or argon gas because such process is commonly known in the art. Therefore in order to protect the genetic samples for long-term storage it would have been within the purview of one skilled in the art to hermetically seal the genetic sample in the borosilicate and tin vials of Kiefer under an inert gas, in order to protect the genetic sample from UV rays and oxygen and moisture, all of which are known to damage and deteriorate DNA (Claims 1, 5, 6, and 33).

Still further, it would have been well within the purview of one of ordinary skill in the art, at the time the invention was made, to place the genetic samples, contained in a UV blocking, hermetically sealed container under an inert gas, in a holding member that is to be placed in a box for long-term storage of the sample (Claim 31). One of ordinary skill in the art would have been motivated to place the sealed container in a holding member for placement in a box in order to not lose the small container comprising the genetic information. The company CATGee, Ltd even provides display kits that comprise holding members for display of the genetic information, which can either be placed in a safe, or displayed in the home. It would be further obvious to one of ordinary skill in the art to place four of the hermetically sealed containers in a single box, in order to store an entire family's genetic information, CATGee, Ltd provides such family DNA kits. Additionally, please note that multiplication or duplication of parts (such as multiplication of the number of holding members in the box) does not impart patentable significance unless a new and unexpected result is produced, see *In re Harza*, 274 F.2d 660, 124 USPQ 378 (CCPA 1960) (Claim 37). It would further be obvious to one of ordinary skill in the art to use any suitable material for the box and holder member of the kit; therefore it would have been obvious to one of ordinary skill in the art to use cardboard box and transparent plastic as the holding members (Claims 39 and 40). One of ordinary skill in the art would have been motivated to use a cardboard box based on the vast availability of cardboard, its popularity as box material, and the simplicity with which it can be

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folded into different box shapes. One of ordinary skill in the art would have been motivated to use transparent plastic material for the holding members because of the malleability of plastic, allowing it to easily be formed to hold the containers. One would have expected success using cardboard and plastic because they are both known in the art to be suitable materials for forming storage containers.

Finally, though Ando et al use plasmid DNA from *E.coli*, and not genomic DNA from blood, it would have been obvious to one of ordinary skill in the art to use any type of DNA, including genomic DNA from blood (Claims 11, 14, and 36). One of ordinary skill in the art would have been particularly motivated to lyophilize genomic DNA from blood when preserving family DNA for future medical testing or genealogy purpose, such as described by Duerinck or by CATGee, Ltd. Duerinck and CATGee, Ltd teach that DNA from blood is best for archiving purposes, as testing labs can run the most thorough tests on genomic blood DNA, particularly for genetic testing purposes. Obtaining genomic DNA from blood samples is routine practice, known to one of ordinary skill in the art (See Gilbert et al). One of ordinary skill in the art would have expected success lyophilizing genomic DNA from blood in the same manner as Ando et al teaches for lyophilization of plasmid DNA, because plasmid DNA and genomic DNA share the same basic structure, and one skilled in the art would recognize that lyophilization of DNA is a routine practice, and thus would expect success (Claims 11 and 14).

Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-12, 14-15 and 31-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Volkin et al (US 2002/0156037), in view of "Kevin Duerinck Genealogy Page" (March 2001) and CATGee, Ltd (Product and Company Info, available before Jan. 2004), and further in view of Cadet et al (Biol. Chem, 1997), Kiefer (US Patent 3,907,586), Labconco ("A Guide to Freeze Drying for the Laboratory," ©1997, available Jan. 1988) and Gilbert et al (Current Protocols in Human Genetics, 1998).

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Applicant's amended claim 1 is directed to a method for long-term storage of hereditary information, comprising providing a genetic sample comprising lyophilized DNA and sugar, wherein the sugars is trehalose or sucrose, in a hermetically sealed UV blocking container under an inert gas, wherein the DNA is substantially free of magnesium; and storing the sample. Claim 5 requires the inert gas to be nitrogen or argon. Claim 6 requires the UV blocking container to comprise borosilicate. Claims 7-9 require specific amounts of DNA to be included in the sample. Claim 10 requires the DNA to be lyophilized. Claim 11 requires the DNA to be obtained from the blood of a subject. Claim 12 requires the sample to be stored at a temperature between about  $-7^{\circ}\text{C}$  to about  $24^{\circ}\text{C}$ . Claim 13 requires the sample to further comprise EDTA. Claim 14 requires the DNA to be genomic DNA. Claim 15 requires a further step of isolating the DNA.

Applicant's claim 31 is directed to a method for long-term storage of hereditary information, comprising providing a genetic sample comprising lyophilized DNA and sugar, wherein the sugar is trehalose or sucrose, in a hermetically sealed UV blocking container under an inert gas, and placing the sealed UV blocking container into a holding member that is inserted into an aperture of a box that together forms a kit for the long-term storage of hereditary information, wherein the DNA is substantially free of magnesium; and storing the sample. Claim 33 requires the inert gas to be nitrogen or argon. Claim 34 requires sample to comprise greater than 20 ug of DNA. Claim 35 requires the sample to be stored at a temperature between about  $-7^{\circ}\text{C}$  to about  $24^{\circ}\text{C}$ . Claim 36 requires the DNA to be genomic DNA. Claim 37 requires the holder member to hold four hermetically sealed containers of the lyophilized DNA and sugar. Claim 39 requires the box to be made of cardboard. Claim 40 requires the holder member to be made of a transparent plastic.

Volkin et al teach a method for providing a genetic sample comprising lyophilized DNA that are stable for storage over a range of temperatures including  $-20^{\circ}\text{C}$ ,  $0^{\circ}\text{C}$ , and  $25^{\circ}\text{C}$  (which applicant calls storage at a temperature between about considered to be about  $-7^{\circ}\text{C}$  to about  $24^{\circ}\text{C}$ ) (See Volkin et al, Pg.

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24, paragraphs 0222-0223). Volkin et al do not teach inclusion of magnesium ions or any component that comprise magnesium; therefore the DNA appears to be substantially free of magnesium. Volkin et al also teach that by including sugars, such as amorphous disaccharides lactose and sucrose greatly stabilized the DNA, in the DNA solution (See Volkin et al, Pg. 24, paragraph 0224). Therefore Volkin et al teach a method of providing a genetic sample comprising lyophilized DNA and sugar (including sucrose) (Claims 10, 12 and 15).

Volkin et al use 20 ug samples of DNA (See Volkin et al, Pg. 24, paragraph 0223); however, it would have been obvious to one of ordinary skill in the art to lyophilize any desired quantity of DNA based on the sample quantity provided or on the needs of the experiments to be carried out. One of ordinary skill in the art would have a reasonable expectation of successfully scaling up the procedure to perform the lyophilization process on any amount of DNA sample provided. It is well established principle in patent law that the mere scaling up of a prior art process capable of being scaled up, does not establish patentability in a claim to an old process or product capable of being scaled up, See *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976). In general, differences in size or proportion do not distinguish the claimed invention from prior art that discloses the same product in a different size or proportion, especially when the difference in size or proportion has no effect on the function of the product (Claims 7-9 and 34).

Though Volkin et al teach methods of providing lyophilized DNA and sugar, wherein the DNA is substantially free of magnesium, they do not teach providing the lyophilized genetic sample in a hermetically sealed UV blocking container under an inert gas. However, at the time the invention was made it would have been well within the purview of one of ordinary skill in the art to provide the genetic sample in a hermetically sealed UV blocking container under an inert gas in order to preserve the genetic sample for long-term storage. One of ordinary skill in the art would have been motivated to preserve the genetic sample for long-term storage because personal long-term storage of ones' own DNA has become

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increasingly popular for security reasons and for family genealogy research. For example, Duerinck suggests archiving ones' family's DNA for future genetic testing, in case a medical problem arises one day, or for genealogical purposes, such as finding relatives. Other companies provide DNA storage services, such as CATGee Ltd, who suggest saving DNA for protection of ones' identity, or as a unique gift (The DNA storage services provided by CATGee Ltd were available before Jan 2004, as evidenced by the article in "UK Trade & Investment" dated 21 April 2003). Therefore, one of ordinary skill in the art would have been motivated to lyophilize their genetic samples, in the method of Volkin et al, in order to allow for long-term storage of the genetic sample. Additionally, in order to protect the lyophilized genetic sample from degradation or deterioration during storage, it would have been well within the purview of one of ordinary skill in the art, at the time the invention was made, to store the lyophilized sample in a UV blocking container under an inert gas. One of ordinary skill in the art would have been motivated to store the DNA sample in a UV blocking container because UV rays damage DNA (See Cadet et al, abstract & Fig. 1); therefore it would have been obvious to one of ordinary skill in the art to store the genetic sample in a container that blocks UV rays, such as the UV blocking borosilicate and tin vials of Kiefer (See Kiefer, abstract & col. 3, ln 63-col. 4, ln 9). One would expect the vials of Kiefer to protect the genetic sample from UV damage because Kiefer teaches the vials effectively protect the contained sample from UV damage (See Kiefer col. 3, ln 63-col. 4, ln 9). One of ordinary skill in the art would also have been motivated to store the DNA sample in the above mentioned container under an inert gas, such as nitrogen or argon because oxygen and moisture are detrimental to DNA (See Labconco, Pg. 7); therefore it is routine practice to apply vacuum to the sample container and backfill with an inert gas such as nitrogen or argon (See Labconco, Pg. 7, col. 2). One would expect success backfilling the vials of Kiefer with nitrogen or argon gas because such process is commonly known in the art. Therefore in order to protect the genetic samples for long-term storage it would have been within the purview of one skilled in the art to hermetically seal the genetic sample in the borosilicate and tin vials of Kiefer under an inert

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gas, in order to protect the genetic sample from UV rays and oxygen and moisture, all of which are known to damage and deteriorate DNA (Claims 1, 5, 6, and 33).

Still further, it would have been well within the purview of one of ordinary skill in the art, at the time the invention was made, to place the genetic samples, contained in a UV blocking, hermetically sealed container under an inert gas, in a holding member that is to be placed in a box for long-term storage of the sample (Claim 31). One of ordinary skill in the art would have been motivated to place the sealed container in a holding member for placement in a box in order to not lose the small container comprising the genetic information. The company CATGee, Ltd even provides display kits that comprise holding members for display of the genetic information, which can either be placed in a safe, or displayed in the home. It would be further obvious to one of ordinary skill in the art to place four of the hermetically sealed containers in a single box, in order to store an entire family's genetic information, CATGee, Ltd provides such family DNA kits. Additionally, please note that multiplication or duplication of parts (such as multiplication of the number of holding members in the box) does not impart patentable significance unless a new and unexpected result is produced, see *In re Harza*, 274 F.2d 660, 124 USPQ 378 (CCPA 1960) (Claim 37). It would further be obvious to one of ordinary skill in the art to use any suitable material for the box and holder member of the kit; therefore it would have been obvious to one of ordinary skill in the art to use cardboard box and transparent plastic as the holding members (Claims 39 and 40). One of ordinary skill in the art would have been motivated to use a cardboard box based on the vast availability of cardboard, its popularity as box material, and the simplicity with which it can be folded into different box shapes. One of ordinary skill in the art would have been motivated to use transparent plastic material for the holding members because of the malleability of plastic, allowing it to easily be formed to hold the containers. One would have expected success using cardboard and plastic because they are both known in the art to be suitable materials for forming storage containers.

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Finally, though Volkin et al use plasmid DNA, and not genomic DNA from blood, it would have been obvious to one of ordinary skill in the art to use any type of DNA, including genomic DNA from blood (Claims 11, 14, and 36). One of ordinary skill in the art would have been particularly motivated to lyophilize genomic DNA from blood when preserving family DNA for future medical testing or genealogy purpose, such as described by Duerinck or by CATGee, Ltd. Duerinck and CATGee, Ltd teach that DNA from blood is best for archiving purposes, as testing labs can run the most thorough tests on genomic blood DNA, particularly for genetic testing purposes. Obtaining genomic DNA from blood samples is routine practice, known to one of ordinary skill in the art (See Gilbert et al). One of ordinary skill in the art would have expected success lyophilizing genomic DNA from blood in the same manner as Volkin et al teaches for lyophilization of plasmid DNA, because plasmid DNA and genomic DNA share the same basic structure, and one skilled in the art would recognize that lyophilization of DNA is a routine practice, and thus would expect success (Claims 11 and 14).

Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### *Response to Arguments*

Applicants' arguments filed 27 March 2006 have been fully considered. It is first noted that the amendments to claims 31 and 37 obviate the objections to these claims; also, the incorporation of the specific sugars trehalose and sucrose into the independent claims obviate the rejections under 35 USC 112, first paragraph as lacking written description and enablement; finally, the amendments to claims 1, 13, 31 and 37 in addition to applicants arguments overcome the claim rejections under 35 USC 112, second paragraph, as being indefinite, unclear, or lacking antecedent basis, except in the instance of the term "substantially free," as discussed above. Applicants' specific arguments will be addressed below.

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In response to the rejection under 35 USC 112, second paragraph, over the term “substantially free” applicants argue that one skilled in the art would understand that substantially free of magnesium would mean free to a great extent or degree.

This is not found persuasive because applicant cannot define a relative term of degree by using other relative terms of degree; the explanation that ‘substantially free’ means ‘free to a great extent or degree’ still fails to precisely define what applicant is intending to claim. The specification fails to set forth general guidelines for interpreting the phrase ‘substantially free’ and the art does not set forth well known ranges which would be accepted as being considered ‘substantially free’ of magnesium; therefore, with no guidelines or reference points, one cannot determine the scope the claimed invention.

In response to the rejection under 35 USC 103(a) over Ando et al (J. Pharm. Sci, 1999) in view of the other cited references, applicants argue that Ando et al teach that lyophilization of DNA resulted in nicked DNA, and therefore Ando et al developed an alternative method (cryopreparation) of preserving the DNA; therefore applicants argue that one skilled in the art, in reading Ando et al, would not use lyophilized DNA as recited in the claim, but instead would use DNA prepared by the cryopreparation technique described therein. Applicants additionally argue that Ando’s failure to recite the presence of magnesium does not teach that the product [of Ando et al] is substantially free of magnesium because magnesium and other trace elements are known in the art to be associated with DNA.

These arguments are not found persuasive.

First, regarding Ando et al’s teachings on lyophilization, while it is recognized that Ando et al teach their method of cryopreparation achieves a higher proportion of supercoiled DNA compared to direct lyophilization of DNA, Ando et al still teach DNA can be directly lyophilized, and that addition of EDTA and/or sugars, including lactose, sucrose, trehalose, maltose, and cellobiose, increase the stability of the DNA. It has been held that a known or obvious composition or process does not become patentable



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simply because it has been described as somewhat inferior to some other product or process for the same use or effect. *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). Therefore, although Ando et al teaches direct lyophilization to be inferior to cryopreparation, they still teach direct lyophilization, especially when sugars and/or EDTA are added, of DNA is a suitable preservation method, and thus reliance on Ando et al to shown obviousness is in fact proper.

Second, regarding Ando et al's silence on the presence of magnesium, it is noted that Ando et al do not teach adding magnesium in any way to the DNA sample, in fact, they do not teach the presence of magnesium in the DNA sample at all. In the absence of any teachings, suggestions, or factual evidence that magnesium was, in fact, present in the DNA sample of Ando et al, it cannot be assumed that the DNA of Ando et al contained any magnesium. Applicant has pointed out that magnesium and other trace elements are known in the art to be associated with DNA; however, while applicant has provided no factual evidence or support of such, it is noted that the DNA utilized in the current method would also inherently contain the same amount of magnesium, and according to the claim, whatever amount of magnesium is inherently present or associated with DNA, is sufficiently low enough so as to render the DNA "substantially free" of magnesium.

In response to the rejections over 35 USC 103(a) over Volkin et al (US 2002/0156037) in view of the cited references, applicant again argues that the failure of Volkin et al to positively recite the presence of magnesium would not preclude one of ordinary skill in the art from recognizing that magnesium would be present.

This argument is not found persuasive. As discussed above with regards to Ando et al, references can only be relied upon for what they teach, since Volkin et al does not teach magnesium, in any concentration in their DNA, it cannot be assumed that magnesium was present in their DNA. Applicants provide no factual evidence or reasoning that would support their assumption that magnesium was present

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in the DNA of Volkin et al in any amount, much less an amount sufficient to exceed the limitation “substantially free.”

*Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

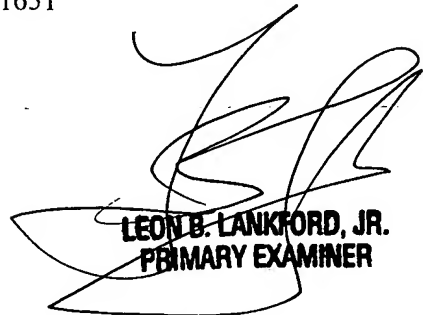
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Allison M Ford  
Examiner  
Art Unit 1651



**LEON B. LANKFORD, JR.**  
**PRIMARY EXAMINER**